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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,521	06/26/2003	Stefan Schafer	DEAV2002/0044US NP	6023

5487 7590 09/14/2004

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT PAPER NUMBER

1614

DATE MAILED: 09/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/607,521	<b>Applicant(s)</b> SCHAFFER ET AL.	
	<b>Examiner</b> Raymond J Henley III	<b>Art Unit</b> 1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 September 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 and 13-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 13-30 is/are rejected.
- 7) ☒ Claim(s) 4-10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1614

**CLAIMS 1-10 AND 13-30 ARE PRESENTED FOR EXAMINATION**

Applicants' Amendment filed September 2, 2004 has been received and entered into the application. Accordingly, claims 1, 2 and 30 have been amended and claims 11-12 have been canceled. In view thereof, the claim rejection under 35 U.S.C. 112, first paragraph as set forth in the previous Office action is withdrawn.

***Claim Rejection - 35 USC § 102/103***

Claims 1-3 and 13-30 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Flynn et al. (U.S. Patent No. 5,430,145), already of record for the reasons of record as set forth in the previous Office action, as applied to claims 1-3 and 11-30.

Applicants' arguments at pages 11-14 of their amendment have been carefully considered, but fail to persuade the Examiner of error in his determination of anticipation/obviousness.

In particular, with respect to the claims being rejected under 35 U.S.C. § 102, applicants have posited at page 12 of the amendment "With respect to the alternative rejection under 35 U.S.C. 102(b) or 35 U.S.C. 103(a) applicants do not consider the claimed subject matter to read exactly on the prior art and thus applicants do not consider the rejection under 35 U.S.C. 102(b) as proper. Applicants have thus responded to the rejection under 35 U.S.C. 103(a)."

Applicants' argument, however, fails to comply with 37 CFR 1.111(b) because it amounts to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the reference.

Art Unit: 1614

Also at page 12 of their amendment, applicants have set forth "Accordingly, applicants respectfully traverse this rejection based on the following arguments. First, as noted above, applicants reiterate that the courts have declined to extract from *Merck & Co. v. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 1843, 1846 (Fed. Cir. 1989) the rule "that regardless of how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it" and "every case particularly those raising the issue of obviousness under section 103, must necessarily be decided upon its own facts." *In re Jones* 958 F.2d at 350-51, 21 USPQ2d at 1943 (Fed. Cir. 1992)..

The above, however, is merely a recitation from the court's decision of *In re Jones*, *ibid*, and not an argument as to why, in the instant case, the present rejection is or is not proper.

At pages 13-14 of their amendment, applicants have argued that the presently claimed subject matter would not have been obvious given the "unexpectedly advantageous or superior properties" which are allegedly demonstrated in the present specification at page 13, lines 15-20 and the experimental data in Examples 1-3 which supposedly establishes a conclusion that the presently claimed compounds possess a superior nephroprotective effect.

This position of applicants fails to overcome the present rejection for several reasons.

First, insofar as the present claims are subject to a rejection based on 35 U.S.C. 102(b), such results are of no moment.

Second, "An affidavit or declaration under 37 CFR 1.132 must compare the claimed subject matter with the closest prior art to be effective to rebut a prima facie case of obviousness. *In re Burckel*, 592 F.2d 1175, 201 USPQ 67 (CCPA 1979)." (see MPEP 716.02(e)). Such would hold true for experimental data appearing in the specification. Here, applicants Examples 1-3 are

Art Unit: 1614

based upon a comparison between a compound of the claims and the ACE inhibitor ramipril. The closest prior art, i.e., Flynn et al. (U.S. Patent No. 5,430,145), however, is not directed to ramipril. Thus, applicants have not offered a comparison between the claimed subject matter with the closest prior art. A proper comparison would be between compounds of the present invention and those of the prior art that are not within the scope of the present claims.

Thirdly, even if a proper comparison were made, applicants have tested only one particular compound and the data relates to only one particular disease type, i.e., the claimed nephropathies. "Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the 'objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support.' In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980)." (See MPEP 716.02(d)). Here, the showing in the specification is not commensurate in scope with the claimed subject matter because the claims are not limited to (a) the particular compound tested, (b) the particular utility for which the results are shown and (c), respecting claim 30, the same statutory category of invention.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

#### ***Claim Objection***

Claims 4-10 are objected as depending from a rejected base claim, but are otherwise in condition for allowance.

Art Unit: 1614

**THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

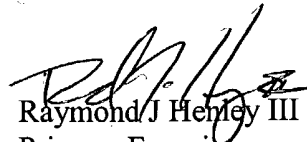
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/607,521

Page 6

Art Unit: 1614

  
Raymond J Henley III  
Primary Examiner  
Art Unit 1614

September 10, 2004